K111716 # 1/5

NOV 10 2011

Core Essence
Orthopaedics, Inc.

510(k) Summary

as required by section 807.92(c).

Knotless Suture Fixation System

K111716

Core Essence Orthopaedics, Inc.

575A Virginia Dr.

Ft. Washington, PA 19034

Jeff Miller

Vice President

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Updated 11/10/11

K111716 #2/5

Submitter:	Core Essence Orthopaedics, Inc. 575A Virginia Dr. Ft. Washington, PA 19034
Contact Person	Jeff Miller Vice President Phone: (215) 310-9534 Email: jeff.miller@ceortho.com

Trade Name	Core Essence Orthopaedics, Inc., TAC-tite™ PEEK
Common Name	Knotless Suture Fixation System
Device Class	Class II
Classification Name and Number	Fastener, Fixation, Non-degradable, Soft Tissue 21 CFR 888.3040
Classification Panel:	Orthopedic
Product Code	MBI
Predicate Devices	Securus Suture Anchors (K090128) Opus® SpeedScrew™ (K100457)
Device Description	Knotless Suture Fixation System includes threaded anchors used to facilitate fixation of soft tissue to bone. This is a knotless suture anchor for surgical treatment of ligament, tendon and soft tissue pathologies of the shoulder and other joints. The implant is constructed of Polyetheretherketone (PEEK) which is widely used for products in the product code.

Intended Use	The Knotless Suture Fixation System is intended to secure soft tissue to bone of: The Shoulder: Bankart Repair SLAP Lesion Repair Acromio-Clavicular Separation Rotator Cuff Repair Capsule Repair Biceps Tenodesis Deltoid Repair

K111716 #3/5

	The Elbow: Ulnar or Radial Collateral Ligament Reconstruction Bicep Tendon Reconstruction Tennis Elbow Repair The Hand and Wrist: Scapholunate Ligament Reconstruction Ulnar / Radial Collateral Ligament Reconstruction Ankle/Foot Indications: Lateral Stabilization Medial Stabilization Achilles Tendon Repair / Reconstruction Hallux Valgus Reconstruction Mid and Rear Foot Reconstruction

Materials:	The implant is manufactured from ASTM2026 implant grade Polyetheretherketone (PEEK) Specifically PEEK-OPTIMA® manufactured by Invibio

Statement of Technological Comparison	The purpose of this submission is to obtain market clearance for the proposed Core Essence Orthopaedics, Inc., Knotless Suture Fixation System. Core Essence Orthopaedics, Inc., Knotless Suture Fixation System and its predicate devices have the same indications for use, similar design, and test results. The device and predicates are manufactured using materials with a long history of use in orthopaedic implants. One of the predicate anchors is made of Ti 6Al-4V ELI (Per ASTM F136 and ISO 5832-2). The new device and the other predicate are made of implant grade Polyetheretherketone (PEEK) (Per ASTM2026).

Summary of Technological Comparison (Please see below)

K111716 #4/5

Nonclinical Test Summary	The following tests were performed to demonstrate that the Knotless Suture Fixation System is substantially equivalent to other predicate devices. • Pullout force • Suture retention The results of these studies showed that the Knotless Suture Fixation System met the acceptance criteria.
Clinical Test Summary	No clinical tests were performed.

Sterilization Information	
Implants	The Knotless Suture Fixation System will be sterilized using EtO. Sterilization validation testing of the process was conducted on equivalent devices to achieve a Sterility Assurance Level (SAL) of 10^{-6}, using the Half-cycle approach, per AAMI/ANSI/ISO/11135.
Instruments and Case	The Knotless Suture Fixation System instrument and case will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted on equivalent product to an Sterility Assurance Level (SAL) of 10^{-6} per ISO 11134.

Conclusion	The Knotless Suture Fixation System is substantially equivalent to its predicate devices. This conclusion is based upon the fact the Knotless Suture Fixation System and its predicate devices have the same indications for use, have a similar design, and similar test results.

Summary of Technological Comparison			
Characteristic	Knotless Suture Fixation System	TAC-tite™ Suture Anchor (Previously cleared Securus) (K090128)	Opus® SpeedScrew™ (K100457)
Intended Use	Same	Same	Both indicated for knotless fixation device for fixation of soft tissue to bone, and examples of procedures are similar.
Material	PEEK-OPTIMA®	Ti6Al4V	PEEK-OPTIMA®
Anchor Type	Screw Type Cancellous Style Buttress Thread	Screw Type Cancellous Style Buttress Thread	Screw Type
Suture Lock	Knotless	Knotless	Knotless
Performance Specs.	Same	Same	Similar

K111515

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Core Essence Orthopaedics
% Mr. Jeff Miller
Vice President
575A Virginia Drive
Fort Washington, Pennsylvania 19034

NOV 10 2011

Re: K111716
Trade/Device Name: Core Essence Orthopaedics, Inc., Knotless Suture Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 2, 2011
Received: November 3, 2011

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111716

Indications for Use

510(k) Number K111716

Device Name: Core Essence Orthopaedics, Inc., Knotless Suture Fixation System

Indications for Use:

The Knotless Suture Fixation System is intended to secure soft tissue to bone of:

- The Shoulder,
  - Bankart Repair
  - SLAP Lesion Repair
  - Acromio-Clavicular Separation
  - Rotator Cuff Repair
  - Capsule Repair
  - Biceps Tenodesis
  - Deltoid Repair
- The Elbow:
  - Ulnar or Radial Collateral Ligament Reconstruction
  - Bicep Tendon Reconstruction
  - Tennis Elbow Repair
- The Hand and Wrist:
  - Scapholunate Ligament Reconstruction
  - Ulnar / Radial Collateral Ligament Reconstruction
- Ankle/Foot Indications:
  - Lateral Stabilization
  - Medial Stabilization
  - Achilles Tendon Repair / Reconstruction
  - Hallux Valgus Reconstruction

Mid and Rear Foot Reconstruction

Prescription Use X **AND/OR Over-the-counter** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael D. Owens for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111716